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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO: ALL CASES	MDL No. 2419 Docket No. 1:13-md-2419 (RWZ)

PREMIER ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTHERN NEW JERSEY, LLC, ET AL'S MOTION TO DISMISS ALL PRODUCT LIABILITY CLAIMS

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INTRODUCTION

Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates, Premier Orthopaedic Associates Surgical Center, LLC, Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D., Thomas Dwyer, M.D., Richard C. DiVerniero, M.D., and Richard Strauss, M.D. (collectively, "Premier Defendants") hereby move the Court to dismiss all product liability claims, by entry of the proposed order attached hereto as Exhibit 1.

BACKGROUND

In response to the compounding and distribution of tainted methylprednisolone acetate ("MPA") by the New England Compounding Company ("NECC") and resultant 2012 fungal meningitis outbreak, multiple plaintiffs filed lawsuits with a variety of claims in forums across the nation.

In February, 2013, all cases pertaining to the fungal meningitis outbreak were consolidated under the Judicial Panel for Multidistrict Litigation ("JPML") into a multi-district litigation ("MDL") centered in Boston, Massachusetts. A Plaintiffs' Steering Committee (the "PSC") was formed to represent the interests of all plaintiffs.

On November 5, 2013, the PSC filed its Master Complaint, making certain allegations broadly against "Clinic Related Defendants," which include the Premier Defendants. (See Dkt. No. 545.) Specifically, the counts levied against the Premier Defendants included: negligence and gross negligence (Count III); battery (Count VII); failure to warn (Count VIII); agency (Count X); civil conspiracy (Count XI); loss of consortium (Count XIII); and punitive damages (XIV). In this first Master Complaint, claims based on violations of individual state consumer protection statutes (Count IV) specifically excluded the Premier Defendants by failing to reference the New Jersey Products Liability Act ("NJPLA"), N.J.S.A. §§ *2A:58C-1 et seq.*, or the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. §§ 56:8-1 *et seq.* (See Dkt. No. 545, p. 64-70.) This purposeful omission was "a conscious decision not to make a claim under [the

NJPLA] because of the specific provision it has … that delivering a product in the course of medical treatment is not selling the product for the purposes of product liability law." (Transcript of Hearing on Motion to Dismiss, June 18, 2014, p. 63, ln. 1-6.)

The PSC filed the First Amendment to the Master Complaint on January 31, 2014, adding to the Master Complaint one count of Civil Conspiracy against specific Tennessee Defendants – the Saint Thomas Outpatient Neurosurgery Center, the Howell Allen Clinic, Debra Schamberg, R.N. and John Culclasure, M.D. (See Dkt. No. 832.) On this same date, the Premier Defendants filed a Motion to Dismiss for Failure to State a Claim. (See Dkt. No. 831.) This Motion included brief discussion of the law under the NJPLA as a basis to dismiss certain counts against the Premier Defendants. The PSC opposed this motion in their March 7, 2014 papers, to which the Premier Defendants replied on March 21, 2014. (See Dkt. No. 980; Dkt. No. 1031.) The PSC filed a sur-reply on April 23, 2014. (See Dkt. No. 1097.)

On June 18, 2014, Judge Zobel heard oral argument on the Premier Defendants' Motion to Dismiss. In the course of this proceeding, plaintiffs' counsel Mr. Martin stated:

> "…I first want to clarify a point which may be a little ambiguous, and that is with respect to the application of the New Jersey Product Liability Act to this motion.
>
> "The master complaint that was filed here does not have any claim under the New Jersey Product Liability Act. The New Jersey committee made a conscious decision not to make a claim under that act because of the specific provision that it has which is different than, as I understand, the Tennessee law, that delivering a product in the course of medical treatment is not selling the product for the purposes of product liability law. So, that act really doesn't have any application to this motion."

(Transcript of Hearing on Motion to Dismiss, June 18, 2014, p. 62 - 63.)

On August 29, 2014, Judge Zobel returned her decision on the matter, dismissing the counts of battery, agency, and civil conspiracy against the Premier Defendants; additionally, Judge Zobel dismissed all claims against the Premier Defendants under the NJCFA. (See Dkt. No. 1360, p. 62-52.) The Premier Defendants' Motion to Dismiss was denied as to the counts of negligence, failure to warn/lack of informed consent, and punitive damages.

On March 6, 2015, the PSC filed the Second Amended Master Complaint, incorporating the allegations from the Master Complaint and the additional count from the First Amendment to the Master Complaint, taking into account the Court's rulings to date. (See Dkt. No. 1719, p. 1, n. 1.) The counts within the Second Amended Master Complaint which stand against the Premier Defendants include: negligence and gross negligence (Count III); failure to warn (Count VIII); loss of consortium (Count XIII); and punitive damages (Count XIV). Once again, the PSC omitted both the NJPLA and NJCFA from the listed statutes within Count IV: Violation of State Consumer Protection Acts. (See Dkt. No. 1719, p. 64-71.)

In New Jersey, individual claims levied against the Premier Defendants in many cases include both allusions to and direct pleadings of violations of the NJPLA. The Short Form of the Master Complaint for New Jersey plaintiffs includes a count directly claiming "Violation of NJPLA." The PSC and moving party have attempted to meet and confer in order to resolve this dispute, however efforts in that regard failed.

As a result, claims against the Premier Defendants under the NJPLA persist. Therefore the Premier Defendants submit this Motion to Dismiss those claims.

STANDARD OF REVIEW

"The standard for a motion for judgment on the pleadings under Fed. R. Civ. P. 12(c), is the same as that for a motion to dismiss under Fed. R. Civ. P. 12(b)." *Campanello v. Port Auth. of New York & New Jersey*, 590 F. Supp. 2d 694, 698 (D.N.J. 2008). Therefore, where the facts are insufficient to cross "the line from conceivable to plausible, [the] complaint must be dismissed" for failure to state a claim upon which relief may be granted. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); Fed. R. Civ. Pro. 12(b)(6). A pleading that merely offers "labels and conclusions" or a "formulaic recitation of the elements of a cause of action" is insufficient. *Id.* at 555. *U.S. v. Blackstone Med., Inc*, 694 F. Supp. 2d 48, 61 (D. Mass. 2010).

To determine whether a complaint is plausible, the Court must first "tak[e] note of the elements a plaintiff must plead to state a claim" under the law. *Ashcroft v. Iqbal*, 129 S.Ct. 1937,

1947 (2009). Then, the Court must disregard allegations that "are no more than [legal] conclusions," which "are not entitled to the assumption of truth." *Id.* at 1950. Finally, the Court must assume that well-pleaded factual allegations are true, "and then determine whether they plausibly give rise to an entitlement for relief" by supporting each element required under the applicable law. *Id.* The requirement of plausible facts presented at the pleadings stage "calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of [proscribed conduct]." *Twombly* at 545.

SUMMARY OF ARGUMENT

Under the applicable standard of review, the PSC fails to allege sufficient plausible facts to prove a required element to sustain a claim under the NJPLA. As the Premier Defendants were not sellers of the MPA and cannot by any construction of the facts be legally defined as such, any claim under the NJPLA must necessarily be dismissed. Further, the NJPLA clearly subsumes all claims under the NJCFA, therefore all such claims against the Premier Defendants must also be dismissed.

ARGUMENT

I. The NJPLA Does Not Apply to the Moving Defendants, Premier Orthopaedic Associates

From 1987 through present, the New Jersey Products Liability Act ("NJPLA" or "PLA") has controlled the vast majority of claims related to harm caused to consumers by a product. The NJPLA provides "one unified, statutorily defined theory of recovery for harm caused by a product, and that theory is, for the most part, identical to strict liability." *In re Lead Paint Litig.*, 191 N.J. 405, 436 (2007) (citing William A. Dreier et al., *New Jersey Products Liability & Toxic Torts Law* § 1:2–1 (2007)).

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product

> causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J. Stat. Ann. § 2A:58C-2 (West). Actionable harms caused by the product "include 'physical damage to property[,] ... personal physical illness [or] injury,' and the like." Lead Paint, 191 N.J. at 437 (citing *N.J.S.A.* 2A:58C–1(b)(2)).

Statutorily, a "manufacturer" is

> (1) any person who designs, formulates, produces, creates, makes, packages, labels or constructs any product or component of a product; (2) a product seller with respect to a given product to the extent the product seller designs, formulates, produces, creates, makes, packages, labels or constructs the product before its sale; (3) any product seller not described in paragraph (2) which holds itself out as a manufacturer to the user of the product; or (4) a United States domestic sales subsidiary of a foreign manufacturer if the foreign manufacturer has a controlling interest in the domestic sales subsidiary.

N.J. Stat. Ann. § 2A:58C-8 (West).

A product seller includes anyone

> who, in the course of a business conducted for that purpose: sells; distributes; leases; installs; prepares or assembles a manufacturer's product according to the manufacturer's plan, intention, design, specifications or formulations; blends; packages; labels; markets; repairs; maintains or otherwise is involved in placing a product in the line of commerce.

Id. However, this definition subsequently and specifically excludes "a provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill or services." *Id.*

The law of the case in this instance allows Count III (negligence) and Count VIII (failure to warn) to survive this motion to dismiss. (See Dkt. No. 1360, p. 52-55.) All claims under the NJCFA were previously dismissed by the Court. (See Dkt. No. 1360, p. 57-59.) However, the PSC's claims under the NJPLA which appear in the short-form complaints were explicitly excluded from the Master Complaint, First Amendment to the Master Complaint, and Second

Amended Complaint. The Premier Defendants' prior motion to dismiss addressed the "Global Claims" of these papers, and Judge Zobel's Memorandum and Order of August 29, 2015 also addressed said "Global Claims" when related to the Premier Defendants, without addressing the issue of claims or allusions that the Premier Defendants violated the NJPLA which appear in the short-form complaints. Such examination was not warranted at that time because the New Jersey Committee of the PSC had deliberately refrained from making any such claims, and their admitted reason for such restraint was that the structure of the NJPLA prohibited them from doing so as the Premier Defendants were not sellers of the product at issue. (Transcript of Hearing on Motion to Dismiss, June 18, 2014, p. 63, ln. 1-6.)

A. Elements Required under the NJPLA

To make a prima facie case for defendant's liability under the NJPLA, the plaintiff must supply facts to support each element required by the Act: "(1) that defendant is a manufacturer, (2) that the product was defective, (3) that the defect existed when the product left defendant's control, (4) that a reasonably foreseeable user was injured, and (5) that the defect was the proximate cause of the plaintiff's injury." *Ebenhoech v. Koppers Indus., Inc.*, 239 F. Supp. 2d 455, 472 (D.N.J. 2002) (citing *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34 (1996)).

B. The Premier Defendants Are Not Subject to Claims Under the NJPLA

The salient element in this analysis is the initial question of whether the Premier Defendants constitute either "manufacturer[s]" or "seller[s]" of the defective product.

i. Healthcare Providers Are Not Manufacturers or Sellers

New Jersey caselaw supports the proposition that heathcare providers – including physicians and hospitals – are not liable for defective medications or medical devices under the NJPLA.

Even prior to 1987, New Jersey "courts have refused to impose strict liability on health care providers." *Johnson v. Mountainside Hosp.*, 239 N.J. Super. 312, 321 (App. Div. 1990). The

rationale for this precept survived the implementation of the NJPLA and is in currently in effect, because "there is a strong public policy rooted in the general welfare that justifies imposing responsibility only on the basis of a want of due care (negligence) rather than on the basis of a defective product (strict liability)." *Id.* The *Johnson* Court sourced this rationale from *Baptista v. St. Barnabas Med. Ctr.*, which declined to decide as whether a hospital should be strictly liable for administration of hepatitis-tainted blood, because in that case the blood was untainted and the record was "wholly inadequate" in the face of this "very important [question] involving highly significant policy considerations." 109 N.J. Super. 217, 223 (App. Div.) *aff'd sub nom. Baptista v. Saint Barnabas Med. Ctr.*, 57 N.J. 167 (1970).

In 1990 the Appellate Division of the New Jersey Superior Court extended into a healthcare context the New Jersey Supreme Court's earlier rationale from a products liability case pre-dating the NJPLA, by holding that the physicians who unknowingly administered HIV-contaminated blood to a patient during surgery were not strictly liable for the 'defective product.' *Snyder v. Mekhjian*, 244 N.J. Super. 281, 292 (App. Div. 1990) *aff'd,* 125 N.J. 328 (1991) (citing *Newmark v. Gimbel's, Inc.,* 54 N.J. 585 (1969)). The *Synder* Court also answered the question left by *Baptista*, holding that "a hospital cannot be held strictly liable for a latently defective product supplied to it by another for its use in rendering treatment." *Id.* at 293.

Generally, the actual creator of the medication is labeled the manufacturer or seller for the purposes of New Jersey Products Liability and faces allegations under that law. *Sinclair v. Merck & Co.*, 195 N.J. 51 (2008) (injured plaintiffs sued manufacturing company under NJPLA where drug was recalled from market); *McDarby v. Merck & Co.,* 401 N.J.Super. 10 (App.Div.2008) (NJPLA applied to defendant manufacturing company when plaintiffs sued for failure to warn about the risks of a drug eventually withdrawn by defendant from market).

ii. The Premier Defendants Do Not Qualify as Manufacturers or Sellers

By the statutory definitions of "manufacturer" and "seller" provided by the NJPLA, the Premier Defendants clearly do not qualify as either. There is no dispute that the Premier Defendants did not in any way "design, formulate, produce, create, make, package, label or construct" the tainted MPA at issue here; that province is entirely NECC's. N.J. Stat. Ann. § 2A:58C-8 (West). The Premier Defendants constitute physicians and ambulatory surgery centers which provide various pain management and other orthopedic services to individuals including Plaintiffs. The Plaintiffs availed themselves of the Premier Defendants' professional services, wherein the use of MPA was incidental to the provision of medical judgment and surgical intervention. Accordingly, the Premier Defendants fall firmly within the exception to the NJPLA articulated above.

Additionally, the caselaw excluding physicians and hospitals from liability under the NJPLA for a defective medication logically extends to the Premier Defendants, who are physicians and ambulatory surgical centers providing certain outpatient pain management and orthopedic medical services not dissimilar from certain medical services provided by hospitals.

iii. The PSC Cannot Provide the Court Sufficient Facts to Support All Elements of the NJPLA

Not only has the PSC failed to allege any facts which would support the first required element under the NJPLA, but the PSC itself admitted that it could not sustain a claim against the Premier Defendants under the NJPLA. Furthermore, up until and through the June 18, 2014 oral argument on the issue, the PSC deliberately refrained from attempting to make any global claim against the Premier Defendants on that basis. To date, there are no global complaints against the Premier Defendants under the NJPLA; instead, only individual plaintiffs have directly pled or alluded to the NJPLA in their short-form complaints, which themselves contain no fact

recitations and depend upon the Master Complaint, First Amendment to the Master Complaint, and Second Amended Complaint for such allegations. As previously stated, these documents contain no allegations that the Premier Defendants were manufacturers or sellers of the tainted MPA administered to Plaintiffs.

C. All Claims Against the Premier Defendants under the NJPLA and NJCFA Must be Dismissed

The standard of review requires that sufficient plausible facts exist to support each required legal element of a claim. The PSC fails here as there are *no* allegations that the Premier Defendants manufactured or sold the tainted MPA; in contrast, the PSC admitted that they refrained from making any claims under the NJPLA because of the legal provision in the Act that would require the PSC to allege that the Premier Defendants were "sellers" of the MPA. The PSC admitted that they are unable to do so under New Jersey law.

As a result of their failure to allege sufficient facts to support every element of a claim under the NJPLA, all such claims which either directly plead or allude to a violation of the NJPLA by the Premier Defendants must be dismissed.

CONCLUSION

For the foregoing reasons the Premier Defendants respectfully request that this Court dismiss all claims against the Premier Defendants under the NJPLA.

Dated: November 5, 2015

Respectfully submitted,

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CERTIFICATION

I certify that in submitting this *Motion*, I caused a copy of the above to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's System, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: November 5, 2015

Respectfully submitted,

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